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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,867	09/05/2003	Brian L. Pagenkopf	119927-1067	8105

7590

08/24/2004

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EXAMINER

SACKEY, EBENEZER O

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/656,867

Applicant(s)

PAGENKOPF ET AL.

Examiner

EBENEZER SACKKEY

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Claims**

Claims 1-16 are pending.

### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Election/Restrictions***

Originally, restriction to one of the following inventions was required under 35 U.S.C. 121:

- I. Claims 1-13 are, drawn to a method of preparing a pyrrole, classified in class 548, subclass 400+.

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- II. Claims 14-16 are, drawn to an additional method of preparing a pyrrole, classified in class 548, subclass 400+.

During a telephone conversation with Thomas Wright on 7/14/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-16 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

However, upon further review and reconsideration, the above restriction has been revised as follows: Group I, claims 1-9 and 11-16 and Group II, claim 10. Applicants have been advised of the change and an election of Group I has been made with traverse on or about 08/16/04.

Note Group II is drawn to a method of using the claimed pyrrole to generate combinatorial libraries, which is classified in class 435, subclass 6+, and may raise separate issues of patentability. Art, which may anticipate or render obvious Group II, would not necessarily do the same for the process of preparation in a similar method of Group I.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-9 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substituted pyrroles of pages 6, 7, 8, and 9 of the specification, does not reasonably provide enablement for making any and all pyrroles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 1 recites a method of preparing a pyrrole comprising the step of reacting a donor-acceptor cyclopropane with a nitrile in the presence of an effective Lewis acid catalyst.

Pyrroles are known in the art and myriad methods for preparing various types can be found as evidenced by U.S. Patent numbers 6,083,971 and 3,250,783. Note in these patents the production of specific types of pyrroles, not any and all pyrroles as alleged herein.

Applicants own publication, "A Powerful New Strategy for Diversity-Oriented Synthesis of Pyrroles from Donor-Acceptor Cyclopropanes and Nitriles", Organic Letters, Vol. 5, No. 26, pages 5099-5101 (2003) states "all attempted nitrile cycloaddition reactions with cyclopropanes other than those prepared by intramolecular cyclopropanation failed to incorporate nitrile" suggesting the unpredictability of the process. The said reference also discloses the sensitivity of the solvent employed, which solvent is clearly absent in claim 1. See the entire reference.

Also, given the dehydration step needed to make the pyrroles, not all the donor groups would be considered viable leaving groups, which are employed in the dehydration step. Also, in the final pyrroles made, ethoxy carbonyl group is always present in the final product suggesting that said group may control regioselectivity.

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The specification provides no other guidance as to what type of "substituted" donor-acceptor reactants are suitable for use in the instant process. Applicant's limited working examples do not enable one of ordinary skill in the art to prepare any and all pyrroles encompassed by the instant invention.

Hence, the specification fails to provide sufficient support of the broad method for preparing pyrroles. As a result necessitating one of ordinary skill in the art to perform an exhaustive search for which particular method can be used in order to practice the claimed invention.

Claims 14-16 are also rejected herein as many of the issues raised above apply herein, ----- i.e., no solvent recitation, no clear description of structural make up of the reactants (note "RO" as carboxylate group, "X" as any ester or ketone group or any  $\alpha,\beta$ -unsaturated derivative, or other "functionalized group etc).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reasons apply:

1.) The phrase "donor-acceptor" is of indeterminate scope. Are hydrogens donor-acceptor groups? First of all, there is no indication of what type of donor-

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acceptor is intended. There are electron, proton etc., types. Even if electron donor-acceptor is intended, the phrase defines what it does, rather than what it is. Functional language at the pint of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ 2d. 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". A definition by function, as indicated, does not suffice to define the process. While there are lists of functional groups in textbooks as examples of such type of groups, the terminology requires testing to determine intended scope.

2.) Also, it appears more than cyclopropane *per se* is being embraced as evidenced by examples in the specification directed to further fused ring systems. Cyclopropane by well-accepted definition is not further fused. Note *In re Hill*, 161 USPQ 229 (CCPA 1969).

3.) The same remark made directly above applies to the nature of "pyrrole" which appears to include carbocyclecyclopropane and tetrahydrofurano fused rings. Note *In re Hill*, *supra*.

4.) It is not clear what is being claimed in claims 3 and 4. If only one substitution is present, how can it be "selectively" positioned? If two or more present, how is it positioned? Germinally? Vicinally?

5.) For claim 5, how can you determine reaction efficiency in the absence of any reaction conditions? Specification provides no guidance as to how to determine structural make up of any cyclopropane in a particular stereochemical configuration.

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6.) Nature of the protective group in claims 6 and 7 is not clear since applicants do not indicate what needs to be protected.

7.) What types of functional groups are included in the phrase "otherwise functionalized" appearing in claims 11 and 14? Specification provides no guidance as far as the Examiner can determine.

8.) Claim 12 depends on itself and claim 13 has a typo, "if" should be ---is---

9.) The scope of claim 13 is completely unascertainable in the absence of any reaction conditions. Product yield in specification employing various reactants vary from 31% to 85%, which suggests the presence of product mixtures.

10. For claims 14-16, various terms are unclear as to structural make up and point of attachment on reactants and final products. See aromatic,  $\alpha,\beta$ -unsaturated, ester, ketone, what type of an ester or ketone group is envisioned etc.

11.) RO as a carboxylate group requires clarification. Is the group a donor or acceptor group? Where is "R" defined?

12.) For claim 16, the claim recites a method in claim 14, wherein compound 4 is a 3,4-dihydro substituted pyrrole. However, 4 in claim 14 is fully unsaturated. Perhaps, 3 was really intended.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's



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supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS  
August 21, 2004

*E Bernhardt (for SPE McKane)*

EMILY BERNHARDT  
PRIMARY EXAMINER  
GROUP ~~126~~ 1600